

THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

**GUIDELINES
FOR
ENVIRONMENTAL HEALTH SCIENCES CENTER GRANTS**

NEW AND COMPETING CONTINUATION APPLICATIONS

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I. INTRODUCTION

The mission of the National Institute of Environmental Health Sciences (NIEHS) is to support research and research training relating to the etiology, mechanisms, diagnosis, treatment and prevention of human diseases and disorders caused by environmental chemicals, pollutants, contaminants, and other factors. To achieve this mission, NIEHS, through the Division of Extramural Research and Training (DERT), employs a number of support mechanisms which are available to investigators. Among these are various types of research grants, including traditional Research Project Grants and Research Program Project Grants, Core Center Grants, and individual and institutional National Research Service Awards (training grants). Research and training areas of interest to the Institute are outlined in our information package, available from the NIEHS Information Office or from the Division of Extramural Research and Training, NIEHS.

The **Center Core Grant (P30)** is an institutional award, made in the name of a principal investigator, to support centralized resources and facilities shared by investigators with existing research projects. Its aim is to stimulate a multidisciplinary approach to a joint research effort. It should be the "intellectual hub" around which research will be supported and stimulated. It is awarded competitively, initially for up to four years, and may be renewed for periods of up to five years. Although no funds are provided for direct support of research projects, except for pilot projects and research program development, a Center Core Grant helps to integrate and promote research in existing projects and provides an administrative framework within one or several central themes. By providing a Center structure, Core resources, and community outreach, this support is intended to enhance the productivity of traditional research grants at the institution and thereby improve the health of the community and nation.

This document provides information on NIH-NIEHS policies and procedures for NIEHS Center Core Grants (P30), including a general description, outline of essential characteristics, administrative requirements, research and facility core requirements, allowable budget items, application process, review procedures, and review factors. It is important to realize that these guidelines are intended to provide meaningful direction and instruction about the core center grant concept and, as such, they are fairly comprehensive and structured. This is not intended to preclude consideration of deviations on a case-by-case basis after discussions with and concurrence by appropriate DERT staff.

II. GENERAL DESCRIPTION

The NIEHS Center grant is a mechanism for providing core support and for integrating, coordinating, and fostering interdisciplinary interaction and cooperation among a group of established investigators conducting high-quality research clearly related to the effects of environmental factors on human health. The intent of the NIEHS in employing this mechanism is

to integrate and build upon existing programs and institutional resources which are already developed, peer reviewed, and supported on an individual project basis.

The NIEHS Center grant should provide an administrative structure and an environment which will strengthen and increase productivity and generate new ideas through organized interdisciplinary collaborative efforts. As such, the NIEHS Center grant provides an added dimension that includes capability and potential for a net accomplishment which will be greater than that possible by the support of individual projects alone. The NIEHS Center grant provides support for core resources and facilities to be used by Center investigators in order to coordinate their activities. This support may include administrative and facilities personnel, equipment, supplies, and services. In addition, it may provide limited funds for program enrichment and for pilot studies. The NIEHS Center grant does not provide direct funding for ongoing research projects. These are expected to be funded through other sources and support mechanisms, mainly individual research grants and program projects awarded by the NIH. Similarly, stipends and tuition for trainees are not available through the NIEHS Center grant funding; such funding must be sought through other mechanisms.

III. ESSENTIAL CHARACTERISTICS OF AN EHS CORE CENTER

The Environmental Health Sciences Centers are a national resource for multidisciplinary approaches to problems in human environmental health. As a group they form a network that fosters communication, innovation, and high-quality research. They are expected to provide a stimulating, multidisciplinary environment that attracts both established and promising young investigators. They are also a key source of expertise to the NIEHS when dealing with emerging issues in environmental health and a means for communicating environmental health issues to the public and to elected representatives. Therefore, a community outreach and education program (COEP), as a means of involvement with local and regional environmental health issues, is a requirement of an NIEHS Center.

At the time of submission of an initial application, any institution or consortium wishing to qualify for the NIEHS Center grant must have an active, established program in basic, clinical, and/or epidemiological biomedical research in environmental health sciences. The existence of an ongoing, extramurally supported biomedical research base is a prerequisite for the establishment and continued support of a Core Center. A minimum of \$1,500,000 (direct costs) of peer-reviewed extramural support for Center-related research in environmental health science is required of applicant investigators at the time of application. The quality of this research base will be evaluated by considering the competitiveness of the funding sources and the breadth of support in the proposed Center (see part E). Consideration in the peer review process will be given to how the proposed Center will further extend and stimulate this research base. Focus on an environmental health science theme, interrelationships among Center members, quality and productivity of the research programs, and demonstrated or potential interdisciplinary coordination are all important considerations.

Over and above the base of a sufficient number of high quality research programs, a number of other factors are essential for an effective EHS Core Center. These characteristics must be demonstrated to reviewers of the application. The degree to which each of the following

characteristics can be documented will be the major determining factor in peer reviewers' evaluation of the application:

A. Interdisciplinary Coordination

There must be evidence of interdisciplinary research that is or will be facilitated by a high degree of interdisciplinary coordination, interaction, and cooperation among Center members. A Center's core support should facilitate creative interactive research activities and should increase efficiency by providing support for shared equipment and centralized multi-user facilities. Examples of interdisciplinary coordination and cooperation resulting from the structure provided by a Center include, but are not limited to:

1. Collaborative, interdisciplinary research efforts.
2. Collaboration among laboratory, clinical, and epidemiological investigators.
3. Publications resulting from such efforts.
4. Significant sharing of facilities and equipment.
5. Seminars involving all Center members.

Scientists or clinicians conducting independent research with limited or nonexistent interdisciplinary interactions cannot be considered to be functioning collectively within a Center. Such individuals are supported independently by more suitable mechanisms, such as individual research grants (R01).

B. Organization and Facilities

The Center must have appropriate and adequate organization and facilities for the conduct and evaluation of Center activities. The facilities and organizational arrangements should stimulate collaboration among constituent programs. Administratively, the Center must have an organizational structure and capacity (including Internal and External Advisory Committees) that supports collaborative research as well as joint planning and evaluation activities. Facilities should be configured so as to optimize usage and interactions among Center investigators and enhance research productivity. Facilities are discussed in greater detail under Facility Cores.

C. Center Director

Each applicant institution will specify a Center Director with adequate authority to be responsible for the organization and operation of the Center. The Director should be an experienced and respected individual who can provide scientific and administrative leadership for the total program. He/she must be able to coordinate, integrate, and provide guidance in the establishment of new programs and direct Center resources to existing programs to maximize productivity. The authority of the Center Director should include the control of appointments to the Center (and by extension, the ability and means to delete individuals from the Center). A Deputy Center Director must also be designated to serve in the absence of the Director, with other responsibilities described.

D. Institutional Commitment

There must be an adequate commitment of the parent institution(s) to the EHS Center. The Center should be recognized as a major element within the organizational structure. Institutional commitment may be manifested by various combinations of personnel, facilities, equipment, provision of space, and financial obligations and commitments.

E. Research Focus in Environmental Health Science

An NIEHS Center grant provides a mechanism for fostering interdisciplinary cooperation in a group of established investigators conducting high-quality research in environmental health science. Therefore, existence of a strong research capability is fundamental to establishment of a new Center or continuation of an existing Center. To qualify for potential Center support, an institution must orchestrate this research capability so as to have a clearly identifiable, major scientific focus in environmental health research. An existing program of excellence in biomedical research in the field of environmental health science is thus a basic prerequisite for establishment of an NIEHS Center. Furthermore, a Center must be able to capitalize upon these research capabilities and resources in order to advance significantly our understanding of its chosen scientific focus.

Research within an NIEHS Center should take advantage of new scientific findings to address an interdisciplinary spectrum of research questions pertaining to environmental health. Such approaches should provide the scientific foundation that ultimately leads to improvement in treatment and prevention of diseases having an environmental etiology. Although the scope of research at an NIEHS Center may be broad, emphasis should be placed on the generation of innovative, cutting-edge approaches and strategies that explore novel hypotheses that can profoundly affect our current level of knowledge. As a result, a Center award should enhance the development of new lines of research as well as the capacity of the host institution to serve as a national resource regarding emerging issues in environmental health.

The scientific focus of an NIEHS Center should be easily identifiable from: 1) the subject matter of the grants which are held by members of the Center and are part of the application; 2) the structure and objectives of Research Cores within the Center; and 3) the manner in which the Center promotes interdisciplinary, interprogrammatic research. Because the purpose of an NIEHS Center grant is to accelerate progress in research and application of research results in human populations, a minimum base of research grant support by proposed Center investigators is required. At the time of submission of a competing application, the proposed Center structure must have a minimum of three active NIH or peer-reviewed research grants on environmental health-related topics totaling at least \$1,500,000 direct cost and awarded during the fiscal year in which the Center grant application is submitted. Those grants qualifying for the \$1.5 million support base should be directly related to the theme of the Center and not a collection of all grants supporting research that might have some connection to environmental health sciences. These grants should have a minimum of two years of funding remaining in the project period, not including any administrative extensions, either with or without additional funds.

Qualifying research grant support should be distributed among the proposed participating Center investigators and be representative of the type of research that the proposed cores can be expected

to enhance. Research grant support from sources other than PHS will be considered on a case-by-case basis if it can be demonstrated to NIEHS staff and to reviewers of the center grant application that: (1) the research is sufficiently related to human health; (2) the grant award is the result of an openly announced and appropriately competitive process; and (3) the grant application was subject to a peer review of comparable rigor to that of PHS. If the qualifying grant base includes other than PHS research grant support, the scientific merit of that research and the degree to which it satisfies the three criteria above may be subject to review by the Environmental Health Sciences Review Committee.

Prior to submission of an application, the proposed Center Director must consult with Institute Staff regarding the adequacy of the research base.

F. Community Outreach and Education

All NIEHS Centers are required to establish and maintain a Community Outreach and Education Program (COEP). The objective of the COEP is translation of research results into knowledge applied to human health. Appropriate activities are further described under IV(F)-COEP.

It is imperative that an NIEHS Center define the community and/or region that it serves and develop productive outreach efforts which are specifically designed to address environmental health issues and problems of greatest concern to that community. It is particularly important to deal with such issues when they arise in a population which may be more susceptible to environmental insults, e.g., children, elderly, or socioeconomically disadvantaged communities. NIEHS Centers are encouraged to sponsor local efforts through community organizations and to collaborate with other existing outreach programs in their area, e.g., those supported by other NIH institutes, other federal agencies (NIOSH, CDC, ATSDR), state or local agencies or health departments.

IV. ORGANIZATIONAL AND OPERATIONAL ELEMENTS OF EHS CENTERS

The bulk of funding for a Core Center is intended to provide an administrative framework and a resource infrastructure for support of research activities of the Center. The Center itself is generally structured to consist of an administrative core, research cores, facility cores, a COEP core, a pilot projects program, and, optionally, an enrichment program. In all cases, emphasis should be on development and support of shared resources or facilities which will benefit and strengthen the Center. Justification for establishment of a Core component should be based on ongoing and competitively funded research programs.

A. Administrative Core

The administrative structure of the Center will, for the most part, be left to the applicant institution (subject to review by NIH peer review mechanisms). NIH's experience has demonstrated that effective development of a Center program requires close interaction between the Center Director, Center investigators, appropriate institutional administrative personnel, staff of the awarding agency, and other members of the institution in which the Center is located. It is expected that organization of the Administrative Core will provide a supportive structure sufficient to ensure

accomplishment of the following:

1. Coordination and integration of Center components and activities.
2. Advice to the Center Director about productivity, effectiveness, and appropriateness of activities and staff of the Center.
3. Interaction with other Centers, the NIEHS, and other appropriate individuals, groups, or organizations.
4. Administration of the Center's pilot project program, including selection of projects and evaluation of the success of the program.

This administrative structure should include establishment of an Internal Advisory Committee, selected from principal investigators and core leaders of the Center, to assist the Center Director in making scientific and administrative decisions. The role of this committee in evaluating relationships of all projects to overall objectives of the Center, assessment of progress of ongoing research programs, and continual reevaluation of use of Center resources should be made clear in the application. This committee may also function in identification and selection of key personnel for recruitment to the Center.

In the case of an extended absence of the Center Director, the appointed Deputy Director will administer the Center during the unavailability of the Director. If the position of Director becomes vacant, a new permanent Director acceptable to the NIEHS and the National Advisory

Environmental Health Sciences Council (NAEHSC) must be appointed as soon as possible by the institution. Deliberations regarding the appointment should involve the NIEHS staff. In general, the NIEHS will require that the new Director have scientific and administrative qualifications comparable to those of the original Director.

In addition to the Internal Advisory Committee, an External Advisory Committee to the Center Director must be established. The External Advisory Committee should consist of a group of four to seven scientists, including a chairperson, at least 75% of whom are from outside the grantee institution. It is inappropriate for any individual associated with the Center or with administrative responsibility for any aspect of the Center to serve on the External Advisory Committee. The function of this committee is to assist in evaluating the merit of the research programs of the Center, the relevance and importance of the individual components to the objectives of the Center, the effectiveness of communications within the Center, the effectiveness of the pilot project program, and the value and anticipated contributions of proposed new Center initiatives. Likewise, the External Advisory Committee is expected to make recommendations concerning the removal of core support from projects no longer considered fruitful or relevant.

The External Advisory Committee should meet at least once annually. The committee may be supplemented by use of ad hoc members knowledgeable in particular areas or segments of the program being reviewed. In competing continuation applications, documentation concerning the functioning and effectiveness of the External and Internal Advisory Committees must be included.

The Administrative Core should also identify one individual with appropriate fiscal expertise who will function as the business manager for the Center. This individual may be located at the Center level, the Department level, or be an institutional business official, but it is important that this one person be responsible for fiscal aspects of the Center grant and be directly involved in its nonscientific management. This person will also serve as the point of contact with the Grants Management staff of NIEHS. The business manager should also be a participant at the meetings of the Internal Advisory Committee to assure that institutional concerns are recognized in the melding of interests of the Core Center and the individual projects. While budget formulation and planning undoubtedly will begin with the Center Director in collaboration with scientific staff, the business manager must be involved deeply in the process and must give final approval. The diversity of support requires that the institution evaluate such things as equipment on hand versus that requested for core facilities, the usage of core facilities by individual research projects, and documentation on equipment maintenance costs borne by individual grants and core center grants. This information should be available to the NIEHS and to site visit review committees.

In addition to its responsibilities for fostering communication and cooperation within the Center and developing program goals which will optimally exploit its resources, interests, and expertise, the Administrative Core must provide a framework through which the Center can work with the NIEHS and with other EHS Centers to meet national environmental health research needs. In order to facilitate communication and dissemination of information and review of problems and national needs in the environmental health sciences, meetings of all Center Directors and appropriate NIEHS staff are held semiannually. Each Center institution and the NIEHS act as host institution on a rotating basis. These meetings are scheduled well in advance and provide a forum for discussion of program accomplishments, needs, etc. by each Center Director and the Director, NIEHS, and his/her staff.

B. Research Cores

Research Cores are designed to consolidate and focus environmental health science research efforts into a series of administrative and programmatic units. These units, each under the leadership of a Core Director or Coordinator, may be organized along disciplinary lines (such as Biochemistry, Epidemiology, Neurotoxicology), other identifiable research areas selected by the applicant, or some combination of these. Whatever organization is chosen, however, each core should be characterized by an essential element of internal cohesion and synergy among its members. In addition, in order to justify a research-based core, the application should address two important review criteria. First, the unit should provide an intellectual resource to the rest of the Center and enhance the activities of the other units. Second, the unit's research activities should provide a program of sufficient scientific merit to be able to provide such a resource. In describing each of these program areas it is important to relate how the program will benefit from inclusion in the Center and what impact each core will have on Center activities as a whole.

The description and plan for each of the individual program areas should include statements of the goals and aims of the core, as well as brief descriptions of the research base for the core. Center investigators should be productive, established, independent researchers. Each Center is required to develop guidelines for Center participation by investigators. Since the Core Center Grant does

not provide direct funding for research projects, the application should contain summaries of research activities being conducted by Center staff rather than protocols. Important aspects to address in this narrative are:

1. Interactions, interrelationships, and cohesiveness of research efforts.
2. Uses of and benefits from Facility Cores.
3. Plans to develop productive collaborations among Core members and other Center investigators.
4. Strength and appropriateness of the peer-reviewed research grant base within the Core.
5. Scientific productivity in environmental health research, particularly joint publications and collaborations.

In the case of renewal applications, the effect that the presence of the Center has had in regard to the foregoing during the funded grant period.

The application should also emphasize new directions in which the core intends to move, how existing staff intend to follow up on new opportunities within their scientific competence, and areas where new staff are likely to be recruited. It is from this discussion that reviewers are likely to infer the sense of innovation and vision among Center investigators which would establish the Core group as a component of a national resource in environmental health research.

Active research grants funded by NIH and other federal agencies supporting biomedical research, which have undergone peer review by study sections, will be presumed to be scientifically meritorious and will be reviewed primarily for appropriateness of core use and for integration in Center programs rather than for scientific merit. Research projects funded from other sources and research contracts from all sources may be reviewed for scientific merit as well as for appropriateness for inclusion in the core and the research base. Projects and investigators may be deleted from the core based on either review criterion. Overall impact of core activities on environmental health science research in the Center, as well as evidence of cohesiveness and interactions among members, research grant base strength, usage of Facility Cores, and productivity will be key determinants of the relative merit assessment of a Research Core.

C. Facility Cores

A major function of a Center grant is for support of Facility Cores which have multiple users. These cores should be designed to furnish groups of Center investigators with some technique, service, or instrumentation in a manner that will enhance the research in progress, consolidate manpower effort, and contribute to cost effectiveness in terms of providing a service at less cost and possibly higher quality than if each investigator were to attempt the same thing individually. Examples of such facilities are: an animal core, an electron microscopy core, a tissue culture core, a pathology support core, a statistical support core, an oligonucleotide synthesis core, an analytical chemistry core, etc. Establishment and continued support for Facility Cores by a Center grant

must be justified on the basis of use by independently funded Center investigators. At least three investigators with independently funded projects with demonstrated need for such a core service form the minimum required research base to establish a core facility. Although use of these cores by pilot projects cannot contribute to the research base for a core, their utilization by pilot projects is encouraged. Use of core facilities by projects funded by research and development contracts will be evaluated on an individual basis. In general, use of Core facilities by contracts must be paid for in full from the contract funds, not from the NIEHS Core Center grant funds.

Additionally, the minimum of three funded investigator users does not in itself provide sufficient justification. Establishment of a Facility Core with a minimal number of users will require adequate and appropriate justification on the part of the applicant. To aid in review of the application, documentation of use of Facility Cores by the research programs of the Center should be done in two ways: (1) by providing information in a tabular format such as that shown in Exhibit II; and (2) by a descriptive narrative of environmental health-related research activities at the institution and any collaborating institutions which rely upon the use of each Facility Core. This narrative may be included within the description of a Research Core or may appear as a separate section of the application, depending upon the nature of the service support being requested.

The application should provide a total operational budget for each Facility Core together with the percentage of support requested from the Center Grant. In the event of a site visit, user logs or similar information used to compile Exhibit II should be available to validate the extent of use and degree of sharing, should the reviewers request it. In the case of new proposed Centers or new Facility Cores within an existing Center, similar information regarding anticipated use of the Cores should be provided.

All core support derived from the EHS Center grant must be acknowledged on RO1 and PO1 applications. Therefore, prior to a site visit for competing renewal applications, Grants Management staff of NIEHS will verify that all existing grants and grant applications included in Exhibit II have included the appropriate budgetary information. When a Center is first established, individual investigator initiated research project grants may include funds for a part of the services that will ultimately be available from the Facility Cores. At the time of renewal (competitive and noncompetitive) individual investigators must remove from the budgets of individual research project grants those costs associated with services that are received from the Center's Facility Cores. The elapsed time before this adjustment is made generally constitutes a very minor overlap since it is usually several months before a new Facility Core is fully functional. It is acceptable for a Center to have nominal charges to individual grantees for Facility Core services. In this case, these are allowable budgetary items in the investigators' individual grants. A mechanism should be proposed in the Center application to monitor these budgetary adjustments and to ensure that Center investigators using Facility Cores can provide a satisfactory explanation of their relation to the Center in their individual grants.

Information in Center renewal applications should generally cover the same points as initial applications. In addition, past performance and accomplishments should be described. The effect of the service provided by a Facility Core on investigator productivity, in meeting stated goals and objectives, and the cost effectiveness of the core should be addressed.

Each Facility Core must have a designated leader who will be responsible for core activities. The application should explain the organization and proposed mode of operation of each core. It should include a plan for prioritizing investigator use of the core as well as a definition of qualified proposed and potential users. This definition need not be too narrow, since some limited use of a core might be an enticement to established investigators in other fields to lend their expertise to the field of environmental health. If the Facility Core also is used to train investigators in special techniques, the extent of and approach to this training should be included. The use of the core for training purposes is encouraged.

D. Pilot Projects

Inclusion of a pilot projects program in NIEHS Centers is strongly recommended. Because they encourage new and creative research approaches, they are considered an important, integral part of the support provided by the NIEHS Centers Program. Therefore, funds should be designated to provide support of short-term research projects to explore the feasibility of new areas of study and new research leads and to enable investigators to collect sufficient data to pursue support through other funding mechanisms. Pilot projects are primarily intended to:

1. Provide initial support for new investigators to establish new lines of research.
2. Allow exploration of possible innovative new directions representing a significant departure from ongoing funded research for established investigators in environmental health sciences.
3. Stimulate investigators from other areas of endeavor to apply their expertise to environmental health research.

As a general rule, approximately 15% of the direct cost budget for each year should be allocated to the Pilot Projects program of a Center. While the administrative framework for management of the Center's pilot projects program is left to the Center Director's discretion, certain minimal requirements must be met. Management of the program must include provision for:

1. A mechanism that ensures preparation and appropriate announcement of the availability of pilot funding.
2. A mechanism for scientific merit review of pilot project proposals. Copies of all proposals, with documentation of their reviews, relative ranking, and final action must be retained by the Center. These records must be available to reviewers in the event of a site visit.
3. A mechanism to maintain a record of subsequent results of each pilot study (abstract, R01 submission, etc.) recipient. This record must be available to reviewers in the event of a site visit for competing renewals. Input by both the Internal Advisory Committee and the External Advisory Committee in management of the Pilot Projects Program is strongly

encouraged.

In competing continuation applications, review of this program will be based on the record of accomplishments, the management of the program, and an assessment of overall potential needs and opportunities. Therefore, in general, a competing continuation application should include:

1. An historical overview of the Pilot Project program.
2. A description of Center management of the program.
3. A listing of all pilot projects which were supported during the last project period, giving the title, amount awarded, investigator, a brief description of the project and, if known, the results and outcome in terms of eventual grant submissions, awards, and publications.

E. Program Enrichment

Limited funds for Center enrichment purposes (e.g., special lectures, visiting professors, symposia, etc.) may be allowed when specifically described and the cost itemized. Justification should be provided for the relationship to the Center as a whole and not to a single, separately funded project.

F. Community Outreach and Education

All Centers are required to develop and sustain community outreach and education activities (see III.F) and are encouraged to collaborate with NIEHS staff in developing printed and audiovisual educational materials. These outreach activities should be identified as programs supported by the NIEHS Environmental Health Sciences Center. Support for appropriate staff positions, travel, equipment, and supplies for this activity is allowed.

The objective of the Community Outreach and Education Program (COEP) is the translation of research information into knowledge applied to public health. Therefore, each center is expected to develop a COEP consistent with the research strengths and focus of the Center. Types of activities incorporated within the COEP may include, but are not limited to, the following:

1. Educational programs in environmental health science for health care providers (physicians, nurses, pharmacists) in the area.
2. Public awareness forums or workshops in the community.
3. Disease prevention and intervention programs, especially those that are community-based.
4. Primary, secondary, or college education in environmental health; development of instructional materials for such curricula; activities to enhance the capacity of teachers in grades K-12 to understand and use environmental health science curricula and materials.
5. Telephone inquiry, online information services, or other informational programs that address environmental health concerns or issues in the community, e.g., radio or television

shows, museum exhibits, and educational programs at community, youth, science, or nature centers.

6. Community issue programs; etc.

Due to the essential nature of this outreach activity and its fundamental significance to NIEHS Centers, it is recommended that the COEP comprise an independent core unit.

(a) The Center should develop a specific plan and set of integrated activities for COEP, particularly with respect to the Center's defined community and target audience. COEP should be a logical outgrowth of the scientific focus of the Center and exhibit the potential for mutual benefit due to interactions with Center research cores and investigators. Activities should be coordinated with the NIEHS Office of Communication to assure consistent policy and avoid duplication of efforts.

(b) It is important to note that COEP is not intended to include human subject research, epidemiology, clinical trials, clinical services delivery, or community-based research. All research projects should be contained within research cores and be separately peer reviewed and funded. However, COEP may be useful, for example, as a means of establishing a productive relationship with a community-based organization, which could subsequently form the foundation of a research grant application. In such cases, appropriate COEP proposals may be considered for pilot project funding. The program should not go beyond public and community education about reducing environmental disease risk and/or hazard exposure recognition as the COEP is not intended to give medical, legal, political, social, or economic advice.

G. Other Center Activities

These are Center facilities that provide highly unique or specialized services or resources to related research programs outside of the Center. These are intended to enable a Center that has highly sophisticated technology available to provide usually expensive services at significantly lower cost or to make available some unique and valuable resource. Requests for these individualized types of core support should be discussed with the NIEHS staff prior to their inclusion in requests for Center funding and are subject to merit review by the EHS Review Committee and to review for relevance to environmental health research by the NAEHS Council.

V. ALLOWABLE BUDGET ITEMS

The appropriate OMB cost principles as modified by the Federal Regulations applicable to these grants and the PHS Grants Administration Manual and Grants Policy Statement govern the general rules of allowability, allocability and reasonableness of costs. These guidelines will be a part of the terms and conditions under which these awards are made. It is important to recognize that, even though a cost may be allowable, it is the responsibility of the applicant to adequately justify the inclusion and amounts of all items for which funding is requested. Should an award be made, it is NIH practice to limit escalation; accordingly, an adjusted escalation factor will be utilized in computing future year costs.

To aid in review of the application, it is recommended that separate budget pages be prepared for each of the Organizational and Operational Elements listed in section IV above:

1. Administrative Core
2. Each Research Core
3. Each Facility Core
4. Pilot Projects
5. Program Enrichment
6. Community Outreach and Education Program

A. Professional Personnel Salaries

For all of the categories of personnel listed below, the requested percentage of an individual's salary may not exceed the percentage of effort devoted specifically to meeting actual Center responsibilities. The total percentage time devoted to Center-related activities, paid or unpaid by the Center, should be stated. Documentation substantiating this level of effort must be included in the application and levels of effort should be described in each appropriate part (core) of the application.

1. Senior Leadership Personnel

This category includes individuals who have responsibility for overall direction of the entire Center. Examples of senior leadership personnel that qualify include the Center director and deputy director.

2. Research, Facility, and COEP Core Leaders

This category includes the designated leaders, directors, or coordinators of the identified Research, Facility, and COEP cores of the application. Program directors or leaders are eligible for salary support under this category for the time and effort they devote to carrying out functions such as research planning, supervision, coordination activities, core administration, and staff training. In addition to these leadership activities, program directors should be active participants in high-quality research such as being a principal investigator on a funded research grant. A description of activities and time estimates for all core directors' functions must be included in the proposal. Core directors will not be funded unless they direct bona fide programs and are judged by peer reviewers of the Center grant to be appropriate leaders of such programs. Individuals identified as Core Leaders or other senior leadership personnel must be designated as key personnel on the application.

3. Center Investigators

Appointment as a Center investigator is an indication of active participation in the Center's interdisciplinary and coordinated approach to research on problems in environmental health. The Center investigator benefits from the appointment by being able to use core facilities, etc., and by participating in the interactive framework of the Center. The Center benefits from the scientific and intellectual input of these investigators. The anticipated result will be a synergistic effect on research programs in the Center due to the existence of

the Center grant. Therefore, no salary support for research activities is allowed except for (a) newly recruited investigators and (b) research program development, both described below.

a. Newly Recruited Center Investigators: The EHS Center grant may provide partial (research) salary support (up to 75%) and laboratory set-up costs for investigators newly recruited from outside the Center organization. This mechanism is intended to be used to develop research programs by providing support for younger investigators who are at the beginning stages of their research careers or to provide a means to add needed expertise to the Center structure. Because the greatest advantage of this type of support is the opportunity to enhance the breadth and depth of the research activities of the Center, most of the Newly Recruited Center Investigators supported are to be recruited from outside the parent Center and host Institution. Likewise, former graduate and postdoctoral students of Center members should not be considered for support unless it can be satisfactorily demonstrated that they have established independent research careers.

Funds awarded under this section may be used for salary, technical support, and equipment. The remaining 25% salary support for the Newly Recruited Center Investigator must be derived from other than Center funds. Research salary support for Newly Recruited Investigators must be less than 75% if the investigator has responsibilities as a Research Core or Facility Core leader and is supported as such. For each investigator, the duration of support as a Newly Recruited Center Investigator will be limited to no more than three years. Specific individuals to be awarded Newly Recruited Center Investigator support need not be identified in the application, but the amount budgeted for this purpose should be declared, and, to the extent possible, the types of individuals sought and their expected roles in the Center described. Competing continuation applications should include a discussion of how these funds were used in the previous project period, in terms of who was recruited and how these individuals benefit the Center programs.

b. Research Program Development: The EHS Center grant may provide research salary support to Center investigators for the purpose of enhancing existing research programs of the Center. This will provide for research to further develop existing areas of research within the Center as opposed to investigating new areas. The latter is provided for in the pilot project category.

Principal Investigators with existing peer reviewed research grant salary support can be supported up to an equivalent level of effort by the Center grant for a period not to exceed two years under this category. Center Directors are required to outline the procedures and policies regarding selection of center investigators for such support. Both the methods of selection and the history of use of such funds will be reviewed and evaluated by the Environmental Health Sciences Review Committee, NIEHS staff, and Council in competing applications and by NIEHS staff in non-competing years.

THE COMBINED LEVEL OF SUPPORT PROVIDED UNDER SECTIONS 3(a) AND 3(b) CANNOT EXCEED 10% OF DIRECT COSTS.

4. Administrative and Technical Support Personnel

a. Salaries and support for Center administrative and clerical personnel, such as the business manager, COEP staff, secretaries, and clerical support staff, may be provided. These costs should not duplicate or replace costs included in the institution's indirect cost rate. Justification for clerical support should describe fully the duties to be performed for each requested position and include information on how many other clerical positions are in the Department or Center, how many are employed by Center investigators, and explain the source of funding for each.

b. Salary support for technical personnel or positions to be filled in Facility Core units may be included. However, the time and salary of all technical and support personnel must be related to a Facility Core or to support of a Newly Recruited Center Investigator. If the individual functions primarily in providing a Facility Core function, justification for the position should refer to Exhibit II, the use record of the core. Appropriate acknowledgment will be verified by the Grants Management staff of NIEHS prior to Center application review. Technical support personnel may receive up to 100% support from the Center, subject to merit review. As a general rule, funds for support of shop personnel and mechanical maintenance should be included as a part of the institutional base for indirect cost calculations and are unallowable as direct costs to the Center. However, in highly unusual circumstances, costs for specialized core facilities which would not otherwise be available at the Institution without the existence of the Environmental Health Sciences Center may be allowable with proper justification and documentation. Prior to including such costs in the application the Center Director is strongly encouraged to discuss proposed costs with program and grants management staff of the NIEHS.

B. Equipment/Facilities

This category includes items for broad use in the Center within a Facility Core. Center grant funding is particularly useful for purchases and operation of large items of equipment which are difficult to justify in individual grant applications. When items of equipment are requested, similar items already available must be reported and a clear justification for the new ones in terms of function must be provided. The application should provide a list of potential users and projects, giving grant numbers if possible. The applicant must also provide, on the budget justification page, any duplicate requests which have been made for funding the equipment requested. Co-funding of expensive items of equipment is encouraged. The requested budget for the equipment should be in the Facility Core providing this service and not in Administrative or Research Core budgets.

C. Supplies

Consumable supplies, such as office materials, glassware, animals, chemicals, etc. may be requested, provided they are items used in common by Center personnel and serve to reduce the cost requirements for individual projects. The requested budget for supplies should be in the appropriate Administrative, Facility, or COEP Core providing this service and not in a Research Core budget.

D. Travel

Appropriate travel requests include:

1. Travel of the Center Director, one other Center scientist, and an administrator to meetings with other NIEHS Center Directors or to other center facilities pursuant to administration of the Center.
2. Travel of scientific, technical, or administrative staff for training that would enhance the quality of a Facility or COEP Core unit operation or travel required to maintain the operation of a Facility or COEP Core unit. However, this must be focused, active, intensive training such as a specific course or workshop as opposed to a session at a national meeting or the equivalent.
3. Travel of Newly Recruited Center Investigators to relevant scientific meetings is permitted, but travel of other scientific staff to scientific meetings or for the purpose of dissemination of research results is not allowed. These costs are more appropriately borne by individual research grants.

All travel should be budgeted within the appropriate core unit.

E. Consultants

Named consultants and members of the External Advisory Committee and their associated costs may be included. Support of consultants must be fully justified in terms of program needs. Cost of visiting scientists and seminar speakers in conjunction with enrichment activities are allowable, but all items must be fully itemized and justified.

F. Pilot Projects

As described previously in Section (IV.D.), pilot projects are strongly encouraged. Therefore, up to 15% (or more with prior approval) of the direct costs of each year's budget should be allocated to the support of pilot projects.

Renewal applications should clearly delineate and report the specific allocations of grant funds to the pilot projects program for each year of funding, providing details as described earlier.

G. Other Expenses

Maintenance contracts on general use equipment, duplication costs for annual reports, computer rentals, etc. may be included if fully justified by the application. Requests for funds for equipment maintenance must specify what items are to be maintained, the total yearly cost for maintaining each item, the main users of the item, any other source requesting funding for maintenance of these items, and the amount being contributed from other sources. Publication costs and page charges related to research results of pilot projects are allowed; however, publication costs and page charges for dissemination of other research results by staff investigators are not allowable. The latter should be paid by individual research grants. Costs of developing, printing, and distributing

educational materials are permissible to the extent authorized by PHS policy. Inclusion of a statement recognizing that the document was created in whole or in part with PHS funds should be included on publications. The requested budget for these expenses should be in the appropriate Administrative, Facility, or COEP Core providing this service and not in a Research Core budget.

H. Alterations and Renovations

Funds for alteration and renovation of existing facilities may be requested so long as required for operation of Center programs. However, NIEHS Staff should be consulted as early as possible in the planning of these facilities for special instructions, limitations, etc. Funds for alterations and renovation will not be allowed unless there will be at least two years remaining on the grant at completion of the proposed alterations and renovations.

I. Contracts and Consortium Arrangements

These are, in general, allowed but require special budgetary and reporting format. The NIEHS staff should be consulted prior to submission for special instructions.

J. Items not fundable under a P30 EHS Center grant include:

1. Direct support of individual research projects.
2. Salary and support for central institutional administrative personnel usually paid from institutional overhead charges.
3. Salary and support for administrative activities such as public relations.
4. Travel of investigators, other than Newly Recruited Center Investigators, to scientific meetings.
5. Page and publication charges for staff investigators.

K. Budget and Duration Limitations

NEW APPLICATIONS: New or first-time applicants can apply for up to four years of support. New applications are limited to requests for no more than \$500,000 in direct costs in the first year; \$600,000 in direct costs in the second year; \$700,000 in direct costs in the third year; and \$800,000 in direct costs in the fourth year. Requests for budgetary increases in years 2-4 must be well justified scientifically and financially, and these justifications will be specifically assessed by the EHS Review Committee. Budgetary increases in years 2-4 of new awards are not automatic, and it is therefore important for applicants to provide sufficient information on proposed expansion of research, facility, and/or COEP cores, pilot projects, etc., to permit evaluation. Both the duration and amount of support are subject to peer review evaluation and NIEHS policy considerations.

COMPETING CONTINUATION APPLICATIONS: Competing continuation (renewal) applicants

can apply for up to five years of support. For renewal budget requests for five years of support, annual direct costs are limited to \$1 million. Both the duration and amount of support are subject to peer review evaluation and NIEHS policy considerations. Exceptions to this limit may be made in consultation with NIEHS officials for special emphasis programs. Some examples of such programs would be: Core support for population-based studies, enhancement of outreach activities, funding of up to \$25,000 for a one-time evaluation of an immediate environmental health crises, or, in certain cases, purchase of specialized equipment or instrumentation. Prior consultation with the NIEHS staff is necessary for any such exception.

VI. APPLICATION PROCESS

A. Pre-application

Interested investigators are strongly urged to consult with NIEHS program staff prior to preparation of an application. It is recognized that preparation of applications for large, multi-investigator grants requires a substantial investment of time, effort, and resources by the Center Director and the applicant institution. During initial conversations, the NIEHS staff can discuss the potential applicant's plans for a Core Center and whether or not they are consistent with the guidelines for Centers and mission responsibilities for NIEHS. The base of peer-reviewed research support to proposed Center investigators must be reviewed by NIEHS staff prior to acceptance of an application. If appropriate, alternate support mechanisms may be suggested.

The potential applicant is strongly advised to submit a Letter of Intent. This letter should include a title of the proposed application, a concise description of the proposed Center, the name, address, and telephone number of the Principal Investigator, and the identities of other key personnel and participating institutions. Although a Letter of Intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains is helpful in planning the review of applications. It allows NIEHS staff to estimate the potential review workload and to avoid conflict of interest in the review. With this information, NIEHS staff will be better prepared to advise and assist the applicant in structuring and completing a formal application. Advice given by the staff should not be misconstrued as authorization for award. Staff will not evaluate or discuss merit of scientific aspects of the proposal.

The Letter of Intent should be sent, by January 1, to:

Dr. Allen Dearry
Program Administrator, Centers Program
Chief, Chemical Exposure and Molecular Biology Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
111 T.W. Alexander Drive
Research Triangle Park, NC 27709
Telephone: (919)541-4943 Fax: (919)541-4937
E-mail: dearry@niehs.nih.gov

B. Preparation of Applications

This section supplements the Information and Instructions for Application for Research Grant (Form PHS 398 rev 4/98) which is included in NIH grant application kits. Because these application forms are designed primarily for individual research grants, additional information is required when used for Center Grants. Except as modified in the following sections, the general instructions should be followed.

1. New Applications: the following information should precede the main text of the application.
 - a. The Face Page and page 2. Item 2 of the face page should be "Environmental Health Sciences Core Center Grant." A title should be chosen to correspond to the major theme of the Center.
 - b. Complete Table of Contents, page 3. (Remember to number all pages consecutively, renumbering the printed application kit page numbers, if necessary).
 - c. Complete consolidated budget for the entire Core Center (page 4). Continuation pages may be used if needed to list all personnel.
 - d. Consolidated, or total, budget for the proposed project period (using page 5 of the application kit).
 - e. To assist in review of the application, a summary table showing the budget summary for all core units and pilot projects for the next budget period should be prepared using a format such as that shown in Exhibit III (see V. Allowable Budget Items).
 - f. Distribution of Professional Effort on this application, arranged in a tabular format such as that shown in Exhibit IV.
 - g. A separate budget for each core unit or activity must be included using duplicates of application kit pages 4 and 5. ("First 12-month period" and "All Years of Support Requested") All proposed costs must be fully justified for both the 12-month and future years budgets as indicated in the PHS 398 instruction sheet. In addition, the budget justification should specify the proportion of each investigator salary that is being requested under each of the investigator categories, i.e., Core leader. Similar justifications should accompany requests for technical personnel.
 - h. Exhibit II, "Use of Core Facilities," should follow budgets.
 - i. A listing, by Principal Investigator, of all grant support held by Center investigators that is related to environmental health research and currently active. Each grant should be listed only once. Information to be included is: Principal Investigator, complete grant, number, title, total project period, total amount, current annual amount. NIEHS-supported grants should be listed first, followed by other NIH grants, other federal contracts and cooperative

agreements, and other sources. Individual postdoctoral fellowships should not be listed.

These data should be consolidated into a table which reflects the following:

- (1) Number and amount of all other NIEHS support.
- (2) Number and amount of other NIH (excluding NIEHS) support.
- (3) Number and amount of other Federal (excluding NIH) support.
- (4) Number and amount of all non-Federal support.

j. The page entitled "Other Support" should be filled out for each investigator for whom support is requested. Information to be included is shown in Exhibit V.

k. Biographical Sketches. The Principal Investigator should be first, followed by other investigators in alphabetical order.

l. The Main Body of the Application. The introduction should concisely present the proposed research strategy, including background information leading to the request for Core Center support, a description of the aims and objectives of the Center, benefits to be achieved by funding as a Center grant, special program resources, and overview descriptions of activities and functions of each Research, Facility, and COEP Core, emphasizing areas of coordination. This should be followed by more detailed presentations of the Administrative Core and the other Core Units, providing the information elaborated in the preceding sections of this Guide.

2. Noncompeting Continuation Applications

A continuation grant application must be submitted annually on Form PHS 2590 at least two months prior to the end of each annual budget period. A central office of the grantee institution has the responsibility for notifying the Center Director of the time for submission of the application and for providing the necessary application kit and computerized face page. Timely submission of continuation applications is essential to avoid possible discontinuity of support. The application should include the following:

- a. A Table of Contents following the face page.
- b. A composite budget for the entire Center for the next budget period. Any change in recommended level of support must be fully explained and justified.
- c. A summary table showing the budget summary for all core units and pilot projects for the next budget (use format such as that shown in Exhibit III).
- d. A listing of all sources of current and pending support for each core investigator including, in an explanatory note, changes in effort and salaries of core personnel.
- e. An itemized budget for each core unit. Use duplicated budget sheets from the application form and fully explain and justify all changes in personnel and other budget items that are

different from those reported in the previous year's budget.

- f. A biographical sketch of any new professional personnel and an explanation and justification of additions to the core.
- g. Fiscal data for the current budget period (follow the Form PHS 2590 instruction sheet). Explain fully and justify expenditures which differ significantly from the awarded budget.
- h. A summary progress report. Follow the Form PHS 2590 instruction sheet, except, at the beginning, give a concise list of new findings with an assessment of each new finding in terms of basic science, application to environmental health and national health policies and decisions.
- i. Summary progress reports for ongoing or completed pilot studies.
- j. Proposed feasibility studies (new starts), including descriptions as indicated in the section on "New Applications."
- k. Regarding publications, list only those published or in press since the last continuation progress report. Publications supported by the Center include those resulting from joint research collaborations stimulated by Center-based interaction and/or Facility Core use, i.e., these publications result from research efforts directly enhanced by the Center. Note that this will most likely not include every publication by every investigator affiliated with the Center.

Note: Public Health Service Grants Policy requires that three reprints of publications resulting from work supported in whole or in part by the PHS grant must be submitted to the awarding component.

Comprehensive Annual Center Report. In addition to the summary progress report required for continuation applications, the Center Director prepares and submits separately, following the conclusion of each budget period, a comprehensive annual report of all activities relating to the Center. This report is submitted electronically. Typically, this report includes:

- (a) An "Introduction and Summary" of research, training and other programs.
- (b) Directors report on major research accomplishments (highlights).
- (c) Detailed progress reports on each research project conducted by Center scientists, grouped according to Research Core unit, with appropriate references and a list of publications since the last annual report.
- (d) A progress report on feasibility or pilot projects.
- (e) A report on the Community Outreach and Education Program including the purpose, communities affected, and evaluation of success of the outreach program in meeting its objectives.

- (f) An administrative report, discussing relevant personnel and other matters.

3. Competing Renewals

Instructions for new applications pertain also to competing renewal applications. In addition, however, competing renewal applications must contain a progress report covering the entire project period of the Center since the initial application or the most recent competing renewal application. This progress report should contain an overall executive summary of the most significant advancements of the Center as well as the complete progress of each of the cores. In addition to information provided in new applications, give:

- a. A list showing changes, if any, in responsible investigators since the most recent competitive review.
- b. The rationale for changes, if any, in percent effort and salaries charged to the Center for each investigator, including technicians and other support personnel.
- c. A list of discontinued or modified Core Units, with an explanation for discontinuation or modification.
- d. A list of all publications and completed manuscripts which have acknowledged Center support and resulted directly from Center-stimulated research during the period covered by the progress report. Do not list publications from prior project periods.

4. Competing Supplemental Applications

Consultation with and approval of NIEHS staff is required before submission of a supplemental application. Note that agreement to accept the application for review does not imply a commitment to fund.

Applications for supplemental funds should be made on Form NIH 398, with the words "Supplemental Application" typed on the face page above the words "Grant Application." Complete the face page for supplemental funds requested and all other items as indicated, then give sufficient detail about the requested addition for adequate evaluation of the proposal. Since the original application may not be available during the review, it is essential that the Center be described to set the stage for the supplemental request. In the overview, all information requested in the "New Applications" section should be included but adjusted to the requirements of the supplement. Give (a) table of contents; (b) composite core units budget for the first 12-month budget period and for future years for each core unit for which supplemental funds are being requested; (c) Summary Tables for each year of requested supplemental support in terms of the entire Center and new efforts or expansion for which the supplement is being requested (Exhibits I-III). In addition, describe events leading to the need for supplemental support. Give a summary progress report for the Center, indicating clearly the research directions leading to the need for supplemental funds and the rationale for the new or expanded activity.

5. Use of Human Subjects and Animal Welfare

Current NIH policy requires approval indicated on items 4 and 5 of the face page of the PHS 398 form for all projects involving the use of human subjects and vertebrate animals whether new, competing renewal, or supplemental. Additional information is required for EHS Center grants, however. For projects funded in whole or in part through federal sources, please provide, as an attachment, a separate list of each individual project involving human subjects and a list of each project involving vertebrate animals in which Center personnel are involved. As a minimum, this list should include the investigator's name, grant or contract number, title of project, and date of the most recent institutional review and certification. Letters from the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) should be included that state that any research (pilot studies or other non-NIH reviewed research) performed under this grant will obtain IRB and IACUC approval.

6. Policy Regarding the Inclusion of Women and Minorities in Clinical Research Studies.

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103 43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59: 14508-14513) and reprinted in the NIH Guide for Grants and Contracts, volume 23, number 11, March 18, 1994.

Investigators may also obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

If research involving human subjects is proposed in the Center application that has not been reviewed according to the current policy, either because it was begun prior to January 1, 1991 or because it is funded by non-NIH funds, provide a description of the study, the population involved, and information related to whether or not the results are expected to be generalizable regardless of gender or race. This will assist the NIEHS in obtaining more complete information as to the make-up of study populations in research supported in any way by the Institute.

7. Application Submission

Applications for all types of NIEHS Center grants--new, competing renewal, and supplemental--competing for funds in a given fiscal year are submitted on a single receipt date announced through a solicitation in the NIH Guide to Grants and Contracts. In general, the schedule shown

below will apply:

Guide Announcement	July - August
Receipt Date	February 1
Initial (Scientific) Review	July
Council Review	September
Start Date	April 1

This schedule and single receipt date allows new applicants sufficient lead time to prepare an application and to plan for implementation if funded. Applicants for competing continuations will have approximately seven months between Council review and the start date. It also permits responsible financial management by the Institute of its Centers Program.

The original and three copies of the completed application should be mailed to the Division of Research Grants. Addressed labels are included in the Form PHS 398 application kits. In addition to those copies submitted to the Division of Research Grants, please send two informational copies, under separate cover, to the Program Administrator (See item IX below). These copies are useful to the staff for planning purposes.

In addition, any appendix material should be mailed directly to the Scientific Review Administrator, Environmental Health Sciences Review Committee. This should be done following acknowledgment of receipt and assignment of the application. Fifteen collated copies of appendix material are requested.

The Center for Scientific Review (CSR) has the responsibility of assigning an application to the appropriate NIH Institute. The Institute assignment is based on the scientific goals of the entire program. The CSR, in consultation with the Institute, makes the decision as to whether or not a given application fits established criteria for a Center grant. All applications for NIEHS Center grants will be reviewed by CSR staff upon receipt for completeness and by NIEHS staff for responsiveness to the requirements set forth in this document. Applications found to be incomplete or nonresponsive will be returned to the applicant organization without scientific review.

VII. NEW CHANGES FOR SUBMISSION AS OF OCTOBER 1996

Effective October 1, 1996, instructions for submitting new (and competing renewal) applications to the NIH have changed as follows:

1. The Social Security Number (SSN) of the Principal Investigator should be provided on the face page of the original application only. The SSN should not be provided on the five copies submitted with the original application, or elsewhere in the application, e.g., top of each application page.
2. Official signatures should appear on the original application only. Do not sign copies or reproduce signatures with copies.

3. When submitting competing renewal applications using the PHS 398 grant application kit, the Personnel Report page (Form JJ) should be provided with the original application only. This page should not be duplicated in copies submitted with the original application.

These measures are being taken to further protect the privacy of individuals identified in grant applications. The NIH requests Social Security Numbers for accurate identification, referral, and review of applications and for management of NIH grant programs. Provision of the Social Security Number is voluntary.

VIII. REVIEW PROCEDURES

A Center grant application assigned to the National Institute of Environmental Health Sciences will be reviewed for scientific merit by the Environmental Health Sciences Review Committee (EHSRC).

A site visit to the applicant institution is usually made to evaluate the overall merit of the application. The site visit team includes members of the EHSRC, consultants who have expertise in major research areas, facilities, and outreach activities of the proposed Center, the EHSRC Scientific Review Administrator, and NIEHS staff observer(s).

A site visit is not a prerequisite, however, for consideration of an application by the EHSRC. Therefore, the application is considered a complete document for review purposes. Furthermore, the applicant should not use the site visit as an occasion for adding core units, research projects, or investigators, for making major changes, or for delivering another exposition of the application. Rather, it should be used by the principal investigator and associates to elaborate on the research program and core units, cost effectiveness and quality control features of the core units, and on other Center activities for which funding is requested, as well as to answer reviewers' questions. The site visit team will not consider any component core unit that is presented for evaluation at the site visit which has not been included in the application. Budgetary changes also will not be considered at the time of a site visit. The findings of the site visit team are reported and discussed by the members of the Environmental Health Sciences Review Committee, which makes the final peer review recommendations and assigns the priority score.

The final review and recommendation on all applications assigned to NIEHS is made by the National Advisory Environmental Health Sciences Council. A chartered subcommittee of the Council, the Centers Subcommittee, is charged with an oversight function of the Environmental Health Sciences Centers Program. The NAEHS Council is the primary body for determining the significance of the application to the program goals and mission of the NIEHS.

IX. REVIEW FACTORS

The primary consideration for a Center grant application is the ability of the Center structure and personnel to bring together quality research activities into an interactive, multidisciplinary operation. Quality scientific research is a prerequisite for the application, and without it the application will fail.

Review criteria for the overall program are:

- A. Anticipated and/or documented impact of the Center grant on the existing scientific programs at the grantee institution.
- B. Qualifications of core scientists and the physical and intellectual environment of the group as a national resource for environmental health research and training.
- C. Existence of a base of ongoing, supported biomedical research of high quality is a prerequisite for establishment and continuation of a Core Center and is an important component of the review.
- D. Multidisciplinary scope of the program.
- E. Degree of interrelationships, collaboration, and synergism of research that might be expected to derive from Center support. The Center should promote creative, innovative, high quality interactive research opportunities such that the whole is greater than the sum of its parts."
- F. Leadership ability and scientific stature of the Center Director and his/her ability to meet the program's demands of time and effort.
- G. Provisions for coordinating Research and Facility Cores. The Center must have appropriate administrative arrangements and facilities that stimulate collaboration among constituent programs and personnel.
- H. Effectiveness of the Center in establishing or continuing a Community Outreach and Education Program that makes maximal use of the Center=s strengths in educating the public and surrounding community with regard to reducing environmental disease risk and/or hazard exposure.
- I. Institutional commitment to the Center.

Review criteria for Research and Facility Cores are:

- A. Scientific merit and justification of the core unit in relation to the overall research activities of the Center and the appropriateness of the requested budget for the unit.
- B. Accomplishments of the overall organization and the proposed core unit to date.
- C. Plans for future directions and the importance of planned research in each core unit in accomplishing the mission of the Center and the NIEHS.
- D. Qualifications, scientific acuity, and imagination, experience, and commitment of investigators responsible for core units.

- E. Integration of the core unit into Center activities and its contribution to the Center as a whole.
- F. Academic and physical environment in which research is being conducted, including adequacy of space, equipment, patients (if applicable), and individual and departmental interaction, both real and potential.
- G. Arrangements for: (a) internal quality control of ongoing research; (b) allocation of funds; (c) day-to-day management; and (d) internal and external communication and cooperation among investigators.
- H. Evidence of cost effectiveness and quality control of Facility Cores.
- I. Institutional commitment to the requirements of a core.
- J. Appropriateness of personnel assignments in terms of functions they will perform.
- K. Appropriateness of equipment, supply, and other requests relative to the activities of each Facility Core.
- L. Advantages, or synergism of research, that might be expected to derive from core support.

X. NIEHS CONTACTS

Programmatic inquiries about EHS Center Grants should be addressed to:

Dr. Allen Dearry
Program Administrator, Centers Program
Chief, Chemical Exposures and Molecular Biology Branch
Division of Extramural Research and Training
Office of Program Development
National Institute of Environmental Health Sciences
P. O. Box 12233
111 T. W. Alexander Drive
Research Triangle Park, North Carolina 27709
Telephone: (919) 541-4943 Fax: (919) 541-4937
E-mail: dearry@niehs.nih.gov

Direct inquiries regarding fiscal matters to:

Ms. Laura Williams
Grants Management Specialist, Centers Program
Grants Management Branch
Office of Program Operations
Division of Extramural Research and Training
National Institute of Environmental Health Sciences

P.O. Box 12233
111 T. W. Alexander Drive
Research Triangle Park, North Carolina 27709
Telephone: (919) 541-7629 Fax: (919) 541-1373
E-mail: willia27@niehs.nih.gov